10. (Twice Amended) The method according to Claim 1, wherein the composition further comprises at least one substance-P and neuropeptide-Y inhibitor compound.

11. (Amended) The method according to Claim 10, wherein the substance-P and neuropeptide-Y inhibitor compound is an extract of *Enteromorpha compressa*.

12. (Twice Amended) The method according to Claim 10, wherein the proportion of substance-P and neuropeptide-Y inhibitor compound is between about 0.1% and about 5% by weight relative to the total weight of the composition.

13. (Twice Amended) The method according to Claim 3, wherein the composition further comprises *Enteromorpha compressa*.

14. (Twice Amended) The method according to Claim 1, wherein the composition further comprises at least one compound selected from the group consisting of extract of *Sophora japonica*, methylsilaryl lactate, copper gluconate and zinc gluconate, and mixtures of these compounds.

16. (New) The method according to Claim 1, wherein the fermented soya peptides have a molecular weight of about 200 daltons to about 20,000 daltons.

17. (New) The method according to Claim 1, wherein the fermented soya peptides have an average molecular weight of about 800 daltons.

18. (New) The method according to Claim 1, wherein the fermented soya peptides are obtained by fermenting a soya peptide with a strain of *Lactobaccillus*.

REMARKS

Prior to entry of this Amendment, Claims 1-15 of the application were pending. In this Amendment, Claims 2 and 15 have been cancelled and Claims 16-18 have been added. After entry of this Amendment, Claims 1, 3-14, and 16-18 are pending in the application. The claims have been amended to clarify the invention. No new matter is introduced by these amendments. Support for new Claims 16-18 may be found in the original claims and at page 3 of the specification.

introduced by these amendments. Support for new Claims 16-18 may be found in the original claims and at page 3 of the specification.

35 U.S.C. 112, First Paragraph

In the Office Action dated July 3, 2002, the Examiner stated:

> Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of stretchmarks, does not reasonably provide enablement for preventing of stretchmarks. The specification does not enable any person skilled in the art which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant respectfully traverses the rejection. Under MPEP 2164.01, the test of enablement "requires a determination of whether th[e] disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention." MPEP 2164.01. Applicant contends that the specification does enable one skilled in the art to make and use the subject matter of the claims.

As amended, Claims 1, 3-14, and 16-18 recite a method of "reducing the formation of...stretchmarks," and Applicant contends that the specification enables one skilled in the art to reduce the formation of stretchmarks. The specification states that "[a] subject of the present invention is thus a cosmetic method for preventing and/or treating skin stretchmarks, characterized in that a composition is applied to that areas of the skin *liable to form* or comprising stretchmarks," (page 2, lines 13-17, (emphasis added)), and "the composition used according to the invention may be applied to areas of the skin *liable to form* stretchmarks, comprising stretchmarks in the process of being formed," (page 2, lines 35-38, (emphasis added)). By using the term "liable to form," Applicant has indicated that stretchmarks do not yet exist, but that the skin is susceptible to stretchmarks or that stretchmarks are likely to form. Further, the specification states that "[a]bout 50% of pregnant women develop stretchmarks, on the thighs, the abdomen and/or the breasts," (page 1, lines 12-14), and the

known to cause the appearance of stretchmarks, such as pregnancy," (page 2, lines 23-29). One skilled in the art would recognize that the recited method could be used to at least reduce the formation of stretchmarks by applying the composition to these areas which are liable to form stretchmarks, *i.e.*, the thighs, abdomen, and/or breasts.

In addition, the specification provides working examples where two compositions were applied to "normal skin" of the thighs, (page 10, line 33-35), where "normal skin" refers to skin without stretchmarks. For the first composition, skin without stretchmarks showed "a tendency toward decreasing the Uf (final elongation)," and "a statistically significant decrease in Uv/Ue (degree of viscoelasticity determining the size of the viscous response relative of the elastic response), of about 14%," (page 15, lines 34-38; page 16, lines 1-2). For the second composition, skin without stretchmarks showed "a statistically significant decrease in Uf...of about 6%[,] a stabilization in Ua/Uf (degree of recovery after stress), [and] a stabilization of Uv/Ue," (page 16, lines 20-25). One skilled in the art would recognize these results as indicating an improvement in tensile strength and/or elasticity. While the exact pathogenesis of stretchmarks is unknown, one skilled in the art may associate an improvement in tensile strength and/or elasticity as reducing the likelihood of stretchmark formation.

In addition, Applicant has submitted a Declaration that describes clinical studies which evidence the efficacy of the disclosed compounds in both treating and reducing the formation of stretchmarks. In the first study, (*i.e.*, **1. A randomized double blind clinical study versus placebo**), seventy-four pregnant women applied a cosmetic cream containing 10% lactic acid (pH 3.5) and *Lactobacillus*-fermented soya peptide, twice daily, (the same protocol as described on page 12 in the specification). In the clinical study, the frequency of stretchmarks was reduced by 50% in those women applying the test cream versus the placebo, which demonstrates that the claimed method results in a reduction in the formation of stretchmarks. Importantly, an independent third party has commented favorably in regard to the results of Applicant's clinical study. (*See* Réalités Thérapeutiques en Dermato-Vénérologie, No. 122, Novembre 2002, p. 39, (included as an Annex to Applicant's Declaration)). The third party notes that "Applicant's study confirms the potential interest in the prevention at least

partially of stretch marks by this new formula.") Therefore, Applicant contends that the patent specification does enable one skilled in the art to at least reduce the formation of stretchmarks.

Therefore, in light of all the foregoing arguments, Applicant contends that the subject matter of the claims are fully enabled by the specification. Applicant requests reconsideration of the rejection of claims 1-15 under 35 U.S.C. 112, first paragraph.

35 U.S.C. 112, Second Paragraph

In the Office Action dated July 3, 2002, the Examiner stated "Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

In particular the Examiner noted "(i) Claims 1-15 are vague and indefinite as it is not clear how the compositions can prevent stretch marks." Applicant respectfully disagrees. As discussed above, while the exact pathogenesis of stretchmarks is unknown, one skilled in the art may associate an improvement in tensile strength and/or elasticity as reducing the likelihood of stretchmark formation. More importantly though, Applicant respectfully disagrees that the claims do not satisfy 35 U.S.C. 112, second paragraph, because one skilled in the art need not know how the compositions prevent stretchmarks to be apprised of the metes and bounds of the claims. For instance, claims 1-15 in part recite a "method for reducing the formation of and/or treating skin stretchmarks, comprising applying a composition to the areas of skin liable to form or comprising stretchmarks," (claim 1, from which claims 2-15 depend). The specification states that the "'prevention of skin stretchmarks' means an action which prevents or at least reduces the formation of stretchmarks...by applying the composition before and during an event known to cause the appearance of stretchmarks, such as pregnancy." As such, Applicant contends that one skilled in the art would recognize that "reducing the formation of stretchmarks" refers to applying the recited composition to areas liable to form stretchmarks, which include skin of the thigh, abdomen, and/or breast, as previously noted.

The Examiner also noted that "(ii) The phrase 'skin liable to form'...is vague and indefinite, as it is not clear what skin is liable to form stretchmarks." Applicant respectfully disagrees. As previously noted, the specification states that "[a]bout 50% of pregnant women develop stretchmarks, on the thighs, the abdomen and/or the breasts," and the "'prevention of skin stretchmarks' means an action which prevents or at least reduces the formation of stretchmarks...by applying the composition before and during an event known to cause the appearance of stretchmarks, such as pregnancy." As such, one skilled in the art would recognize "skin liable to form" as including the skin of the thighs, abdomen, and/or breast.

The Examiner also noted that "(iii) The phrase 'soya peptides and tripeptides' in claims 1 and 2 (lines 6-7; line 7) is vague and indefinite." Claim 1 has been amended to more clearly recite the subject matter being claimed, and Claim 2 has been cancelled, which obviates the rejection.

The Examiner also noted that "(iv) The phrase 'fermented soya peptides and tripeptides' in claim 2 (line 7) is vague and indefinite." Claim 2 has been cancelled, which obviates the rejection.

The Examiner also noted that "(v) Claims 3, 8, and 13 contain the trademarks/trade names Phytokine and Kollaren-CPP....The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product." Claims 8, and 13 have been amended to delete the trademarks/trade names. Although Claim 3 does recite the trademark/trade names Phytokine® and Kollaren-CPP®, Applicant contends that the claim scope is not uncertain because the amino acid composition of the fermented soya peptide sold under the brand name Phytokine® is described in the patent specification at pages 3-4 and the synthetic tripeptide sold under the brand name Kollaren-CPP® is described in the patent specification at page 4. Therefore, one skilled in the art would recognize the metes and bounds of the claims when read in light of the specification.

The Examiner also noted that "(vi) The phrase 'a-hydroxyacid' in claims 5 and 7 (lines 2) is vague and indefinite." Claims 5 and 7 have been amended to recite α-hydroxyacid.

The Examiner also noted that "(vii) Claims 8 and 13 are vague and indefinite [in regard to whether] the soya peptide and the tripeptide [are both present] in combination with the lactic acid." Claims 8 and 13 have been amended to more clearly recite the subject matter being claimed.

The Examiner also noted that "(viii) Claim 15 provides for the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass." Claim 15 has been cancelled, which obviates the rejection.

Therefore, in light of all the foregoing arguments and amendments, Applicant contends that the subject matter of the claims fully complies with 35 U.S.C. 112, second paragraph, and Applicant requests reconsideration of the rejection.

35 U.S.C. 101

In the Office Action dated July 3, 2002, the Examiner stated "Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process...is not a proper process claim under 35 U.S.C. 101." Claim 15 has been cancelled, which obviates the rejection.

35 U.S.C. 103

In the Office Action dated July 3, 2002, the Examiner stated "Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,614,215) in view of Shaffer et al. (5,760,079) in further view of Moy (5,759,555), Blanc-Ferras et al. (6,114,336), and De La Charriere et at. (2001/0014342)."

As amended, Claims 1, 3-14, and 16-18 recite a composition that comprises "at least one anti-stretchmark agent selected from the group consisting of *fermented* soya peptides, tripeptides consisting of the amino acids glycine, histidine, and lysine, and mixtures of the fermented soya peptides and tripeptides" (emphasis added). While Ribier *et al.* teaches compositions comprising hydrolyzed soya peptides, Ribier *et al.* does not teach the peptides of the present invention. The soya peptides in Ribier *et al.*, at least implicitly, have a high molecular weight because they require lipid vesicles (*i.e.*, depth vesicles, see column 7 line 14, and Example 3) for dispersion to the deep

layers of the skin. In contrast, Applicant's peptides have a low molecular weight, (*i.e.*, preferably "between about 200 and about 20,000 daltons," see page 3 of the specification), and as such, Applicant's peptides are dispersed to the deep layers of the skin without the need of lipid vesicles. (*See* Declaration at A – ACTIVE INGREDIENTS, page 3, and at C – SUMMARY, page 6). Therefore, Applicants's fermented soya peptides are different than the soya peptides disclosed by Ribier *et al.*, and in fact, Ribier *et al.* teaches away from Applicant's invention. Because Ribier *et al.* does not teach the fermented soya peptides of Applicant's invention (or the synthetic tripeptides of Applicant's invention), none of the cited references, alone or in combination, teach all the elements of the claimed composition, and Applicant respectfully requests reconsideration of the rejection of claims 1-15 under 35 U.S.C. 103.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date 1/2/03

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MARKED UP VERSION SHOWING CHANGES MADE

Below are the marked up amended claim(s):

1. (Amended) A [Cosmetic] method for reducing the formation of [preventing] and/or treating skin stretchmarks, comprising applying a composition [characterized in that a composition is applied] to [the] areas of skin liable to form stretchmarks or having [comprising] stretchmarks, the [this] composition comprising, in a suitable vehicle, at least one anti-stretchmark agent selected [chosen] from the group consisting of fermented soya peptides, [and] tripeptides consisting of the amino acids glycine, histidine, and lysine, and mixtures of [these] the fermented soya peptides and tripeptides.

3. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim 1, wherein [characterized in that] the anti-stretchmark agent is selected [chosen] from the group consisting of the fermented soya peptide Phytokine®, [and] the tripeptide Kollaren-CPP®, and mixtures of [these] the fermented soya peptide and tripeptide.

4. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim 1, wherein [characterized in that] the proportion of anti-stretchmark agent is between about 0.1% and about 10% by weight relative to the total weight of the composition.

5. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim 1, wherein [characterized in that] the composition further [also] comprises at least one [a]α-hydroxyacid[, in combination with the anti-stretchmark agent].

6. (Amended) The [Cosmetic prevention and/or treatment] method according to Claim 5, wherein [characterized in that] the α-hydroxyacid is lactic acid.

7. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim 5, wherein [characterized in that] the proportion of [a]α-hydroxyacid

is between 0.1% and about 20% by weight relative to the total weight of the composition.

8. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim [1]3, wherein [characterized in that] the composition further comprises lactic acid [and an anti-stretchmark agent chosen from the group consisting of the soya peptide Phytokine® and the tripeptide Kollaren-CPP® and mixtures of these peptides, in combination with lactic acid].

9. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim 1, wherein [characterized in that] the composition further [also] comprises a compound for adjusting the pH to a value of between about 2 and about 4.

10. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim 1, wherein [characterized in that] the composition further [also] comprises at least one substance-P and neuropeptide-Y inhibitor compound.

11. (Amended) The [Cosmetic prevention and/or treatment] method according to Claim 10, wherein [characterized in that] the substance-P and neuropeptide-Y inhibitor compound is an [the] extract of *Enteromorpha compressa*.

12. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim 10, wherein [characterized in that] the proportion of substance-P and neuropeptide-Y inhibitor compound is between about 0.1% and about 5% by weight relative to the total weight of the composition.

13. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim [1]3, wherein [characterized in that] the composition further comprises *Enteromorpha compressa.* [and an anti-stretchmark agent chosen from the group consisting of the soya peptide Phytokine® and the tripeptide Kollaren-CPP® and mixtures of these peptides,]

14. (Twice Amended) The [Cosmetic prevention and/or treatment] method according to Claim 1, wherein [characterized in that] the composition further [also]

comprises at least one compound selected [chosen] from the group consisting of extract of *Sophora japonica*, methylsilaryl lactate, copper gluconate and zinc gluconate, and mixtures of these compounds.

16. (New) The method according to Claim 1, wherein the fermented soya peptides have a molecular weight of about 200 daltons to about 20,000 daltons.

17. (New) The method according to Claim 1, wherein the fermented soya peptides have an average molecular weight of about 800 daltons.

18. (New) The method according to Claim 1, wherein the fermented soya peptides are obtained by fermenting a soya peptide with a strain of *Lactobaccillus*.

ABSTRACT

B1

A method for preventing and/or treating skin stretchmarks is described. The method is characterized in that a composition is applied to the areas of skin liable to form or comprising stretchmarks. The applied composition includes peptides in a suitable application vehicle, and the composition displays good skin tolerance.